RH-I-13 MEDICAL USE OF RADIOACTIVE MATERIAL UNDER GENERAL LICENSE CONDITIONS AND LIITATIONS OF GENERAL LICENSE

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§ 4.22-H Medical Diagnostic Uses

- 1. A general license is hereby issued to any physician to receive, possess, transfer, or use radioactive material set
 Forth below for the stated diagnostic uses, provided, however, that the use is in accordance with the provisions of § 4.22-H-2, 3
 and 4, the radioactive material is in the form of capsules, disposable syringes, or other prepackaged individual doses; and the
 radioactive material has been manufactured in accordance with a specific license issued by the commissioner pursuant to § 4.28G, or by the U.S. Nuclear Regulatory Commission, any Agreement State or a Licensing State pursuant to equivalent regulations
 authorizing distribution to persons generally licensed pursuant to § 4.22-H or its equivalent:
 - a. iodine-131 as sodium iodide for measurement of thyroid uptake;
 - b. iodine-131 as iodinated human serum albumin (IHSA) for determination of blood and blood plasma volume;
 - c. iodine-125 as iodinated human serum albumin (IHSA) for determination of blood and blood plasma volume;
 - d. cobalt-57 for the measurement of intestinal absorption of cyanocobalamin;
 - e. cobalt-58 for the measurement of intestinal absorption of cyanocobalamin; and
 - f. cobalt-60 for the measurement of intestinal absorption of cyanocobalamin, and
 - g. chromium-51 as a sodium radiochromate for the determination of red blood cell volumes and studies of red blood cell survival time.
- 2. No physician shall receive, possess, use or transfer radioactive material pursuant to the general license Established by § 4.22-H-1 until he has filed Agency Form RH-F-13, "Certificate – Medical Use of Radioactive Material Under General License" with the commissioner and received from the commissioner a validated copy of the Agency Form RH-F-13 with certification number assigned. The generally licensed physician shall furnish on Agency Form RH-F-13 the following information as may be required by that form:
 - a. name and address of the generally licensed physician;
 - b. a statement that the generally licensed physician is a duly licensed physician (authorized to dispense drugs) in the practice of medicine in this State; and
 - c. a statement that the generally licensed physician has appropriate radiation measuring instruments to carry out the diagnostic procedures for which he proposes to use radioactive material under the general license of § 4.22-H and that he is competent in the use of such instruments.
- 3. A physician who receives, possesses, or uses a pharmaceutical containing radioactive measuring material Pursuant to the general license established by § 4.22-H-1 shall comply with the following:
 - a. He shall not possess at any one time, pursuant to the general license in § 4.22-H-1 more than:
 - (1) 200 microcuries (7.4 MBq) of iodine-131
 - (2) 200 microcuries (7.4 MBq) of iodine-125
 - (3) 5 microcuries (185 kBq) of cobalt-57
 - (4) 5 microcuires (185 kBq) of cobalt-58
 - (5) 5 microcuries (185 kBq) of cobalt-60, and
 - (6) 200 microcuries (7.4 MBq) of chromium-51;
 - b. he shall store the pharmaceutical until administered in the original shopping container, or a container Providing equivalent radiation protection;
 - c. he shall use the pharmaceutical only for the uses authorized by § 4.22-H-1;
 - d. he shall not administer the pharmaceutical to a woman with confirmed pregnancy or to a person under 18 years of age; and
 - e. he shall not transfer the radioactive material to a person who is not authorized to receive it pursuant to a license issued by the commissioner, the U.S. Nuclear Regulatory Commission, any Agreement State or Licensing State, or in any manner other than in the unopened, labeled shipping container as received from the supplier, except by administering it to a patient.
- 4. The generally licensed physician possessing or using radioactive material under the general license of § 4.22-H-1 shall report in duplicate to the commissioner, any changes in the information furnished by him in the "Certificate Medical Use of Radioactive Material Under General License," Agency Form RH-F-13. The report shall be submitted within 30 days after the effective date of such change.
- 5. Any person using radioactive material pursuant to the general license of § 4.22-H-1 is exempt from the Requirements of Part V and Part IX of these regulations with respect of the radioactive material covered by the general license.